JAN 1 9 2001

510(k) Summary

K003481

1. Company Identification

Codonics, Inc.
17991 Englewood Drive
Middleburg Heights OH 44130
Telephone: (440) 243-1198
Fax : (440) 243-1334
Email: www.codonics.com

2. Official Correspondent

Gary J. Allsebrook, Regulatory Affairs
16303 Panoramic Way
San Leandro, CA 94578-1116
Tel.: (510) 276-2648
Fax.: (510) 276-3559
Email: regman1@home.com

3. Date of Submission

July 30, 2000

4. Device Name

Classification Name:	Medical Image Hard Copy Devices (Printers) were evaluated by the Radiology panel and are classified in Class II per 21 CFR §892.1680.
Common/Usual Name:	Medical Image Printer
Proprietary Name:	Codonics NP-1660 Series Medical Printers

5. Substantial Equivalence

The NP-1660 Series Medical Printer is substantially equivalent to the ***Agfa Drystar Series Medical Printers*** and; the ***Kodak XLS 8600 Series (PS), K#951948)***. The device is also known as ***Kodak Ektascan 2000PS*** . Please note that the 8600 is discontinued and product literature for its successor device, the 8650r is included in the Substantial Equivalence section.

Both devices utilize both thermal sublimation and/or direct thermal imaging technology. A detailed comparison chart is located in item 10.

6. Device Description and Intended Use

The NP-1660 Series Medical Printers are an intelligent, dye diffusion/direct thermal dual mode, color and grayscale output device which provides both 10Mb/s Ethernet and Centronics compatible parallel interfaces. The printer accepts many industry standard file formats and includes built-in image processing and spooling capabilities.

7. Software

Codonics, Inc. certifies that the NP1660 software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance.

8. Hazard Analysis

Hazard analysis on this product has been performed throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes, and their effects;
- Development of methodologies to control the occurrence of hazards and to constrain their effects; and
- Determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product are no different than those of other PACS components . These are primarily related to failure of computer system components, and may be variously obviated by decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is "Minor".

9. Safety Concerns

The device was submitted and passed the following electrical safety tests: CAN/CSA-C22.2 No. 950-M89, UL 1950, second edition, and TUV, EN 60950:1992 and EN 60950/A1:1993.

10. Substantial Equivalence

The following product(s) provide functions, which are substantially equivalent to this product:

Manufacturer:	Codonics	Agfa	Kodak
Product Name:	NP 1660 Series	Drystar Series	Ektascan 2000P (Kodax XLS 8600(PS))
510(k) Number:	[redacted]	Unknown	K951948
Print Technology:	Thermal Dye Sublimation	Thermal Dye Sublimation	Thermal Dye Sublimation
Media Sizes:	7 Sizes, 8"x10" to 8.5"x14"	8"x10", 14"x17"	8.5"x11", 8.5"x11.7"
Resolution:	300 Pixels per inch	300 Pixels per inch	300 Pixels per inch
Color/Grayscale Output:	16.7 Million Colors, 256 Levels of Cyan, Magenta, and Yellow or Gray	16.7 Million Colors, 256 Levels of Cyan, Magenta, and Yellow or Gray	16.7 Million Colors, 256 Levels of Cyan, Magenta, and Yellow or Gray
Density Range:	Media Dependent	Media Dependent	Media Dependent
Interfaces:	Ethernet/Parallel (Centronics)/Optional Magneto Optical	Ethernet/Parallel (Centronics)	SCSI/Centronics
Network Protocols:	FTP,LPR,Telnet (TCP/IP), Ethertalk	Ethernet (DICOM TCP/IP)	Ethertalk, NetBeui, TCP/IP
Image Formats:	TIFF, GIF, PCX, BMP, PBM, PGM, PPM, XWD, JPEG, Sun Raster, SGI, Targa/Optional: DICOM, DEFF, PostScript	DICOM, Video	TIFF, GIF, PCX, BMP, PBM, PGM,
Image Formatting:	Variable Multiformatting (VMF), Fixed Multiformatting (FMF), 35mm SlideMaker, Captions and Bracketing	Multiformatting, 1 on 1, 2 on 1, 4 on 1, 6 on 1, 9 on 1, 20 on 1 (slideformat)	Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 9 2001

Codonics, Inc.
Gary J. Allsebrook
C/O Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO, CA 94578-1116

Re: K003481
Codonics, NP 1600 Series Medical Printer
Dated: July 28, 2000
Received: November 9, 2000
Regulatory class: II
21 CFR 892.2040/Procode: 90 LMC

Dear Mr. Allsebrook:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003481

Device Name: Codonics, Inc., NP-1660 Series Medical Printers

Indications For Use:

The Codonics NP-1660 Series Medical Printers are thermal print engines intended to produce continuous tone, photographic quality, hard copy output with a medical color matching feature that adjusts printed output colors to more accurately match CRT monitors. The device will output diagnostic quality prints or transparencies from digital images acquired from a variety of sources such as local area networks (LAN), Internet, or directly from digital capture or storage devices. The printer accepts digital images in TIFF, GIF, PCX, BMP, PBM, PGM, PPM, XWD, JPEG, Sun Raster, SGI, Targa/Optional: DICOM, DEFF and Postscript. Lossy data compression is not employed in the device.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003481